UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., AKORN, INC., MYLAN PHARMACEUTICALS INC., and MYLAN INC., Defendants.	Civil Action No. 2:15-cv-1455-WCB (Consolidated) LEAD CASE JURY TRIAL DEMANDED

MYLAN PHARMACEUTICALS INC., AND MYLAN INC.'S OPPOSITION TO ALLERGAN, INC.'S MOTION TO COMPEL DISCOVERY

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Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. ("Mylan") oppose Plaintiff Allergan, Inc.'s ("Allergan") Motion to Compel Discovery (ECF No. 205) ("Mtn").

Allergan seeks production of information that it has either already received or is irrelevant to infringement by incorrectly conflating the concepts of bioequivalence and infringement. Bioequivalence is not a legal concept; rather, it is a determination made by U.S. Federal Drug Administration ("FDA"). Further, Allergan fails to show—nor can it show—how any of the claims of the patents-in-suit relate to bioequivalence—***none*** of the asserted patents recite claim elements regarding bioequivalence.

Nonetheless, Mylan has produced its ANDA, all amendments thereto, and all FDA correspondence in compliance with the Local Patent Rules. Yet, Allergan insists that it is entitled to additional information—in some cases, information Mylan does not have—simply because Allergan incorrectly asserts that bioequivalence is the test to determine infringement. It is not. That Mylan somehow has *legal contentions* that its ANDA product is bioequivalent to the alleged commercial embodiment of the asserted patents, Restasis®, even though bioequivalence is determined by FDA, is inconsistent with law and fact. Accordingly, Allergan's motion should be denied.

I. BACKGROUND

On March 8, 2016, Allergan served its first set of interrogatories, including Interrogatory Nos. 3 and 5. Ex. 4 to Mtn. Mylan responded on April 11, 2016 and subsequently met and conferred with Allergan regarding its responses. Following this meet and confer, Mylan supplemented its responses to Interrogatory Nos. 3 and 5 on December 1, 2016. Ex. 5 to Mtn.

On December 2, 2016, Allergan moved to compel Mylan to once again supplement its responses to Interrogatory Nos. 3 and 5 (ECF No. 205). In an effort to resolve the issue, Mylan supplemented Interrogatory No. 5 for a second time on December 13.

Interrogatory No. 3 states:

Identify the persons at Mylan most knowledgeable regarding

(a) medicaments for treating dry eye disease;

(b) use of a cyclosporine-A emulsion to treat dry eye disease;

(c) topical medicaments for treating dry eye disease;

(d) ANDA No. 205891;

(e) your Paragraph IV Notifications; and

(f) Restasis®.

Interrogatory No. 5 states:

> Describe fully and with particularity the basis for the assertion in ANDA No. 205894 that Your Proposed Product is bioequivalent to Restasis®, and identify the persons most knowledgeable about the information requested in this interrogatory.

Although Allergan relies on bioequivalence in their infringement contentions, bioequivalence is separate and distinct from infringement and wholly irrelevant to the infringement inquiry.

II. ARGUMENT

A. Mylan's Response to Interrogatory No. 5 is Sufficient and Up to Date

1. *Bioequivalence is not relevant to any issue in this case*

Interrogatory No. 5 is premised on a legal fallacy; it assumes that Mylan has some sort of legal contention that its ANDA product is bioequivalent to Restasis®. Mylan has no such legal contention given that FDA—not Mylan—determines bioequivalence. 21 C.F.R. § 320.21. Aside from the information provided in Mylan's ANDA and FDA correspondence, it is unclear what more information Mylan can provide.

Allergan argues that Mylan's "contentions" of bioequivalence to Restasis®—an alleged commercial embodiment—are purportedly relevant to infringement. Mtn at 4-5. But Allergan does not—and cannot—point to a single claim *in any* of the asserted patents that is directed to bioequivalence. *See Eli Lilly and Co. v. Wockhardt Ltd.*, No. 1:08-cv-1547-WTL-TAB, 2010 WL 2195436, at *2 (S.D. Ind. May 27, 2010) (denying production of bioequivalence studies because movant failed to show relevance). In contrast to what Allergan would have this Court

believe, bioequivalence is not the test for infringement. The test for infringement—which Allergan disregards—is the comparison of the accused product to the asserted claims, none of which relate to bioequivalence. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) ("Infringement, literal or by equivalence, is determined by comparing an accused product not with a preferred embodiment described in the specification, or with a commercialized embodiment of the patentee, but with the properly and previously construed claims in suit."); *see also Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d 1372, 1377 (Fed. Cir. 2008) ("The determination of infringement is a two-step process, wherein the court first construes the claims and then determines whether every claim limitation, or its equivalent, is found in the accused device."); *Atlantic Thermoplastics Co. v. Faytex Corp*., 970 F.2d 834, 846 (Fed. Cir. 1992) ("This court has repeatedly emphasized that infringement analysis compares the accused product with the patent claims, not an embodiment of the claims.").

Notwithstanding the appropriate test for infringement, Allergan argues that because Mylan has submitted an ANDA to FDA representing bioequivalence to Restasis®, Mylan's ANDA product is equivalent to Restasis®, and therefore infringes particular claims in the asserted patents. Mtn at 2. First, Allergan has the burden to show that Restasis® embodies the claims in the asserted patents and has yet to provide any such evidence. *Cf. Media Techs. Licensing, LLC v. Upper Deck Co.*, 596 F.3d 1334, 1339 (Fed. Cir. 2010) (stating it is the patentee's burden to show "that the successful product is the invention disclosed and claimed in the patent" (internal citations omitted)). Second, Allergan's theory, however attenuated, is simply incorrect. FDA defines bioequivalence as "*the absence of a significant difference* in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents *or pharmaceutical alternatives* becomes available at the site of a drug action when administered at the same molar dose under similar conductions in an appropriately designed study." 21 C.F.R. § 320.1(e) (emphasis added). Therefore, if FDA concludes an ANDA product is bioequivalent to a reference listed drug, it is not determinative of infringement.

In fact, the Federal Circuit in *Abbot Laboratories v. Sandoz, Inc.*, a case Allergan relies on to support its incorrect contention that it is entitled to *additional* discovery of Mylan's bioequivalence information, contradicts Allergan's assertions of relevance. In *Abbot*, the Federal Circuit stated that bioequivalency is an inquiry different from infringement, even under the doctrine of equivalents:

> While bioequivalence may be relevant to the function prong of the function-way-result test, bioequivalency and equivalent infringement are ***different inquiries***. Bioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes. In contrast, equivalency for purposes of patent infringement requires an element-by-element comparison of the patent claim and the accused product, requiring not only equivalent function but also equivalent way and result. Different attributes of a given product may thus be relevant to bioequivalency but not equivalent infringement and vice versa. As the Northern District of Illinois observed in the *Sandoz* case, "***[i]f bioequivalency meant per se infringement, no alternative to a patented medicine could ever be offered to the public during the life of a patent***." Thus, while potentially relevant, ***the bioequivalency of an accused product with a product produced from the patent at issue is not sufficient to establish infringement by equivalents***.

566 F.3d 1282, 1298 (Fed. Cir. 2009) (internal citations omitted) (emphasis added); *accord Reckitt Benckiser Inc. v. Watson Labs., Inc.*, 430 F. App'x. 871, 874, 878 (Fed. Cir. 2011). As stated above, Allergan is already in possession of Mylan's bioequivalence information, which was cited in Mylan's original and supplemental responses to Interrogatory No. 5.

2. *Allergan already has the information that it seeks*

Mylan's supplemental interrogatory response is sufficient as it identifies all information that Mylan has submitted to FDA regarding bioequivalence. FDA ultimately will determine the bioequivalence of Mylan's ANDA product. Mylan submitted to FDA that its product meets FDA's guidelines on bioequivalence, and provided related information thereto. Allergan already received all of those communications and related information, and Mylan identified them in response to Interrogatory No. 5.

Further, FDA has provided new guidance on bioequivalence since Mylan's original submission, and to the extent that Mylan has responded to that guidance, Mylan has complied

with the Local Patent Rules and produced all FDA correspondence to Allergan. Mylan has even identified in its supplemental response particular FDA correspondence regarding an amendment made in light of the revised February 2016 draft guidance. Ex. 1. Moreover, although it disputes the relevance of such information, Mylan agreed to provide corporate testimony regarding what activities Mylan is conducting in preparation to respond to FDA's most recent bioequivalence guidance.

Despite Allergan's repeated insistence that it receive Mylan's "contentions" for bioequivalence, any such assertions, even if appropriate, have no bearing on the inquiry of infringement, nor is it a question Mylan can answer without referring to FDA correspondence, which Mylan has already done. Thus, Allergan has failed to identify what information, if any, outside of Mylan's ANDA, is relevant to the question of infringement. Nor has Allergan identified information Mylan should produce that it has not already committed to producing, *e.g.*, any additional FDA correspondence.

Allergan's only discernable complaint is that Mylan has not identified documents in its supplemental interrogatory response that are related to the draft guidance FDA issued in October 2016—***less than two months ago*****.** Mtn at 3, 5. This complaint is unreasonable. As Mylan explained during meet and confer, Mylan has and will continue to comply with Local Patent Rule 3-8(f) and timely produce all FDA correspondence.[1] Thus, to the extent that Mylan responds to FDA's October 2016 guidance, Allergan will receive that correspondence. Allergan has not provided any explanation, during meet and confer or in its motion, of why that is not sufficient.[2]

[1] Local Patent Rule 3-8(f) requires production of FDA correspondence, not all documents underlying that correspondence. The deadline for substantial document production in this case was August 26, 2016 (ECF No. 170). Mylan has no obligation to continually collect documents regarding bioequivalence on an ongoing basis in light of the parties' agreement to an email cutoff date of the original complaint. Ex. 2.

[2] To the extent that Allergan seeks this information in an attempt to bolster its Citizen's Petition, this is an improper litigation tactic and is not relevant to the question of infringement.

B. Interrogatory No. 3 Is Overbroad and, To the Extent Understood, Directed to Expert Testimony

With respect to Allergan's Interrogatory No. 3, other than an identification of persons most knowledgeable about ANDA No. 205891 (Mylan's ANDA), which Mylan has already identified (*see* Ex. 5 to Mtn.), the other topics on which Allergan seeks knowledgeable persons are not relevant to the issues in this case or elicit information that is already available to Allergan, is the subject of expert testimony, or is privileged.

Although Allergan claims in conclusory fashion that an identification of persons at Mylan most knowledgeable regarding (1) medicaments for treating dry eye disease; (2) use of a cyclosporine-A emulsion to treat dry eye disease; and (3) topical medicaments for treating dry eye disease in parts of the interrogatory is "plainly relevant," Allergan fails to articulate any basis for its relevancy claim. Notably, these categories are not tied in any relevant manner to Mylan's accused product. Mylan explained during the meet and confer that, to the extent Mylan plans to offer testimony on these subjects, it will be (as it was during claim construction) through expert testimony. Allergan has failed to respond to Mylan's request for an explanation of relevancy, both in the parties' meet and confer and in its motion.

Regarding the persons at Mylan most knowledgeable about Mylan's Paragraph IV notifications, again, Allergan fails to explain why the identification of such persons is relevant to any claim or defense at issue in this litigation. Allergan already has Mylan's Paragraph IV notifications, which were signed by Mylan's outside litigation counsel. Mylan explained during the meet and confer that those at Mylan with knowledge about Mylan's Paragraph IV notifications are lawyers, and that communications related to Mylan's Paragraph IV notifications are privileged. There is simply no reason, other than harassment, that Allergan requires identification of those lawyers.

Finally, regarding the persons at Mylan most knowledgeable about "Restasis", the scope of this category is so vague and broad that any identification would not be possible, let alone reasonable. As Mylan explained during the meet and confer, the interrogatory fails to identify

what knowledge concerning "Restasis" Allergan is seeking. There are multiple categories of information concerning Restasis and Allergan has failed to respond to Mylan's request for clarification or address with particularity the scope of this category. Mylan already produced its ANDA and all non-privileged documents related thereto. Mylan has also agreed to provide corporate testimony regarding the development of Mylan's ANDA product, including related testing of Restasis, and Mylan's forecasting related to its ANDA product.

Interrogatory No. 3 is so overbroad and ambiguous that it forces Mylan to speculate as to what information Allergan seeks. It also elicits expert testimony which is premature at this stage of the litigation, and improperly calls for the disclosure of privileged information. Allergan has failed to properly identify what relevant, non-privileged information is necessary, beyond what it has already received from Mylan, and therefore its motion should be denied.

III. CONCLUSION

Allergan's interrogatories are overbroad and directed to information irrelevant to the question of infringement. Accordingly, Mylan asks that the Court deny Allergan's request for additional supplementation of Mylan's responses to Interrogatory Nos. 3 and 5.

Dated: December 16, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a) on December 16, 2016. Because the document was filed under seal, counsel has served this document on all counsel of record via e-mail. *See* Local Rule CV-5(a)(7)(C), (c).

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